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The MacNew Heart Disease Health-Related Quality of Life Questionnaire in Patients with Angina and Patients with Ischemic Heart Failure

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ABSTRACT

Objective: Patient-reported outcomes including health-related quality of life are important in clinical care and research studies. The MacNew Heart Disease health-related quality of life questionnaire has been validated in English-speaking patients with myocardial infarction. The aim of this study was to validate the MacNew in English-speaking patients with angina or ischemic heart failure. **Methods:** Canadian and American patients with angina or ischemic heart failure completed the MacNew, the Short Form-36 Health Survey, and the Hospital Anxiety and Depression Scale. **Results:** We administered questionnaires to 276 patients with angina (mean age, 65.9 years) and 155 patients with ischemic heart failure (mean age, 70.3 years). The mean \pm SD MacNew global score in patients with ischemic heart failure (5.1 ± 1.2) was statistically ($P < 0.001$), but not clinically, poorer than in patients with angina (5.3 ± 1.1). The three-factor measurement model explained 46.1% of the observed variance in the MacNew in patients with angina and 46.5% in patients with ischemic heart failure. Internal consistency

was ≥ 0.90 , and test-retest reliability was ≥ 0.70 for each MacNew scale and the a priori convergent and discriminative validity hypotheses were confirmed in both diagnoses. The MacNew was highly accepted by patients with little respondent or administrative burden. **Conclusions:** The English version of the MacNew is reliable and valid in patients with angina or ischemic heart failure. This permits health-related quality of life outcome comparisons in patients with angina, ischemic heart failure, and myocardial infarction with the MacNew and provides a better understanding of the full range of health-related quality of life outcomes.

Keywords: angina pectoris, coronary artery disease, health status, ischemic heart failure, patient-reported outcomes, quality of life, questionnaire.

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Introduction

Patients with ischemic heart disease (IHD) present on a continuum of events that includes the presence of risk factors, angina, myocardial infarction (MI), and ischemic heart failure, often with marked health-status deficits including poor health-related quality of life (HRQoL). As the patient's own perspective of the impact of disease and its treatment, patient-reported outcome measures such as HRQoL have been recommended in both clinical care and research studies by the National Heart, Lung and Blood Institute [1], the U.S. Food and Drug Administration [2], and the European Medicines Agency [3]. Generic HRQoL outcome measures permit assessment of a wide range of aspects of life applicable to a variety of health states and are useful in conducting general health survey research [4]. Specific HRQoL outcome measures focus on disease-relevant issues and are appropriate outcome measures in both therapeutic intervention trials [4] and routine clinical care [5] but should be used only in patients with the disease/diagnosis for

which the instrument is validated and not with an "off-label diagnosis."

A core disease-specific HRQoL questionnaire approach with adequate generalizability and sufficient specificity has been available for about two decades to make between-diagnosis outcome comparisons, for example, in oncology [6,7] and rheumatology [8]. Between-diagnosis HRQoL outcome comparisons are not possible with commonly used IHD diagnosis-specific questionnaires with specific cues such as "your chest pain, chest tightness, or angina" in the Seattle Angina Questionnaire [9] and "your heart failure" in the Minnesota Living with Heart Failure Questionnaire [10]. Increasingly, patients with different IHD diagnoses receive similar treatment, e.g., medication, percutaneous or surgical revascularization, and referral to secondary prevention cardiac rehabilitation, often with common therapeutic goals including symptom management and improvement of HRQoL [1]. A core IHD-specific HRQoL questionnaire with a cue such as "your heart problem" would be useful in clinical practice and research studies allowing between-diagnosis treatment outcome comparisons, would be ef-

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ficient, and would provide a better understanding of the range of HRQoL in patients with different IHD diagnoses.

The interviewer-administered Quality of Life after Myocardial Infarction questionnaire was designed to evaluate how MI and its treatment affects patients' daily life and was validated [11] in English-speaking Canadian patients participating in a randomized trial of cardiac rehabilitation [12]. This questionnaire was subsequently modified as the self-administered MacNew Heart Disease HRQoL questionnaire and validated in English-speaking Australian patients with MI [13,14]. The MacNew has since been translated into 28 languages with independently published validation studies in 8 of these languages in patients with MI ($n > 4300$), angina ($n > 1800$), and ischemic heart failure ($n > 550$) [15–26].

As the psychometric properties demonstrated in patients with MI [27] have been replicated in non-English-speaking patients with angina or ischemic heart failure [17–20,22,23,26], the MacNew may provide a core IHD HRQoL questionnaire for making between-diagnosis comparisons of HRQoL outcomes. There are no validation studies, however, of the MacNew in English-speaking patients with either angina or ischemic heart failure. The objective of this study was therefore to investigate the reliability and validity of the English version of the MacNew in patients with angina or ischemic heart failure.

Methods

Patients

English-speaking patients with a diagnosis of angina or ischemic heart failure were recruited in Canada and the United States as part of the HeartQoL Project, an international survey of HRQoL in more than 6300 patients with IHD in Australia, Europe, and North America [28]. Institutional review boards approved the HeartQoL Project at each site, and informed consent was obtained from all subjects.

A convenience sample of patients 18 years of age and older able to complete the self-administered battery of HRQoL instruments in English, without serious psychiatric disorder, and not a substance abuser were eligible if they had a diagnosis of and being treated for either:

Angina (Canadian Cardiovascular Society Grade II [slight limitation of ordinary physical activity], grade III [marked limitation of ordinary physical activity], or grade IV [inability to carry on any physical activity without discomfort] [29]) with an objective measure of IHD (e.g., previous MI, exercise testing, echocardiography, nuclear imaging, angiography) or ischemic heart failure (New York Heart Association functional class II [patients with cardiac disease resulting in slight limitation of physical activity], functional class III [patients with cardiac disease resulting in marked limitation of physical activity], or functional class IV [patients with cardiac disease resulting in the inability to perform any physical activity without discomfort] [30]) with evidence of left ventricular dysfunction (ejection fraction $\leq 40\%$ by invasive or noninvasive testing) and an objective measure of IHD (e.g., previous MI, exercise testing, echocardiography, nuclear imaging, angiography).

Questionnaires

The referring physician completed a questionnaire for routine diagnostic data, and all patients completed a self-report sociodemographic and clinical questionnaire, including health behaviors. In addition, the Short Form-36 Health Survey (SF-36), the Hospital Anxiety and Depression Scale (HADS), and the MacNew were completed by all patients at baseline and again 2 weeks later by the first approximately 20% of the patients whom the site investigator considered to be in a stable condition.

SF-36

The SF-36 is an internationally validated generic health survey [31]. It consists of 36 items with 8 subscales summarized in a physical component summary (PCS) and a mental component summary (MCS) scale [32].

HADS

The HADS is a validated psychological screening instrument designed to screen for symptoms of anxiety and depression [33]. It is responsive and has been extensively used internationally in clinical trials with scores of 8 or higher used to classify patients with symptoms of depression or anxiety [34].

MacNew

The MacNew is designed to assess patient's feelings about how IHD affects daily functioning and contains 27 items with a global HRQoL score and physical limitation, emotional, and social function subscales [13,14], with a summary of international results available [35]. The items and scales are scored from 1 (low HRQoL) to 7 (high HRQoL), and the minimal important difference (MID) on each MacNew scale is 0.50 points [36]. The readability level of the English MacNew has been established to be on average between the fifth and sixth grade level [37].

Statistical analysis

Patient clinical and sociodemographic characteristics are described as either dichotomous or continuous variables. HRQoL scale scores (mean \pm SD) were calculated using established scoring criteria for each instrument. Comparisons between the two cardiac diagnostic groups were made using analysis of variance (ANOVA) (continuous variables) and chi-square (χ^2) (categorical variables). Assumption for ANOVA (normality and homoscedasticity) was tested by Kolmogorov-Smirnov, skewness, and kurtosis statistics. If data did not meet the necessary criteria, the Welch test (F) was used or the nonparametric Kruskal-Wallis H test was applied.

Using recommended criteria [38] as described in detail below, the conceptual model, reliability, validity, interpretability, and respondent and administrative burden of the MacNew were assessed for patients with angina and for patients with ischemic heart failure. Face and content validity of the MacNew has been previously documented [35].

The original factor structure identified by Valenti et al. [14] was the basis for the confirmatory factor analysis that was carried out using AMOS 18 [39]. Because χ^2 statistics are dependent on sample size, a recommended range of parameters less sensitive to sample size was selected. The χ^2/df , root mean square error of approximation (RMSEA) and comparative fit index (CFI) were used to evaluate data fit. Acceptable values are <5 for χ^2/df [40], >0.90 for the CFI and <0.08 for the RMSEA, with an RMSEA of 0.0 indicating a perfect, 0.05 a good, and 0.08 a reasonable fit [41]. Measurement errors of the items were allowed to intercorrelate where appropriate. Further, differential item functioning (DIF) was assessed [42]. A DIF analysis assesses whether items are functioning equivalently across important categories, such as diagnosis (angina or ischemic heart failure). A minimum difference in scores of 0.5 logits ($P < 0.01$) was used. DIF analysis was performed using WINSTEPS 3.67 [43].

Internal consistency (Cronbach α) and 14-day test-retest reliability (intraclass correlation coefficient [ICC]) were assessed using $r \geq 0.70$ as the criterion value for both tests. With a priori predictions hypothesizing strong correlations between similar SF-36 and MacNew constructs and significantly lower correlations between dissimilar constructs (<0.10 = absent, 0.10 – 0.29 = weak, 0.30 – 0.49 = moderate, and ≥ 0.50 = strong), we tested the MacNew for construct validity using Steiger's test for comparing Pearson correlation coefficients [44,45]. We assessed discriminative validity [46]

Table 1 – Sociodemographic and clinical characteristics of patients with angina and patients with ischemic heart failure.

Patient characteristics	Angina (n = 276)	IHF (n = 155)
Age in years	65.9 ± 11.4	70.3 ± 12.3
Sex		
Male	171 (62.0)	124 (80.0)
Female	105 (38.0)	31 (20.0)
Family status		
Single	45 (16.3)	20 (12.9)
Married	180 (65.2)	102 (65.8)
Other	41 (14.9)	32 (20.6)
Employment		
White collar	122 (44.2)	75 (48.4)
Blue collar	96 (34.8)	45 (29.0)
Education		
Less than high school	55 (19.9)	41 (26.5)
High school	100 (36.2)	55 (35.5)
More than high school	120 (43.5)	58 (37.4)
Anxious (HADS score ≥8)	76 (27.5)	33 (21.3)
Depressed (HADS score ≥8)	56 (20.4)	36 (23.0)
Body mass index	29.5 ± 6.5	28.5 ± 6.0
Smoker	36 (13.0)	21 (13.5)
Functional status		
	CCS II: 154 (55.8)	NYHA II: 56 (36.1)
	CCS III: 100 (36.2)	NYHA III: 87 (56.1)
	CCS IV: 11 (4.0)	NYHA IV: 6 (3.9)
Hypertensive	193 (69.9)	105 (67.7)
Diabetic	83 (30.1)	65 (41.9)
Hypercholesterolemia	205 (74.3)	101 (65.2)
Physically inactive*	150 (54.5)	113 (73.0)

Values shown are mean ± SD or number (%). Data missing when <100%. CCS, Canadian Cardiovascular Society; HADS, Hospital Anxiety and Depression Scale; IHF, ischemic heart failure; NYHA, New York Heart Association (functional class).

* Exercised less than three times/week.

testing the hypotheses that HRQoL would be 1) poorer in anxious and depressed patients than those who were not using the HADS and 2) poorer in patients who perceived that their health had or had not deteriorated over the past year using the SF-36 health transition item. We also report on the interpretability of the MacNew scores relative to the published MacNew MID (≥0.5 points) and on respondent and administrative burden.

SPSS version 16.0 (SPSS, Inc., Chicago, Illinois) was used for all statistical analyses. Statistical significance was established at $P \leq 0.05$.

Results

Patient characteristics (Table 1)

A convenience sample of 431 patients was recruited with a mean ± SD age of 67.5 ± 11.9 years, and 297 (68.9%) were male. The mean ± SD age in the 276 patients with angina was 65.9 ± 11.4 years and 70.3 ± 2.3 years in the 155 patients with ischemic heart failure. In the angina group, 13.0% reported they were current smokers and 54.5% exercised less than three times per week; 69.9% reported that their physician had told them they were hypertensive, 30.1% diabetic, and 74.3% with high cholesterol. In the ischemic heart failure group,

13.5% reported they were current smokers and 73.0% exercised less than three times per week; 67.7% reported that their physician had told them they were hypertensive, 41.9% diabetic, and 65.2% with high cholesterol. There were no patients with either Canadian Cardiovascular Society or New York Heart Association functional class I per study design, and only a few with Canadian Cardiovascular Society angina class IV (4.0%) or New York Heart Association heart failure functional class IV (3.9%).

MacNew, SF-36 health status, anxiety, and depression (Table 2)

MacNew subscale scores could be calculated in all 431 patients, SF-36 subscale scores in 409 patients (94.9%), and HADS scale scores in 427 patients (99.1%).

Patients with angina had better HRQoL than patients with ischemic heart failure with significantly higher scores on the MacNew global, physical, and social subscales and on the SF-36 PCS but not the MCS. The HADS anxiety scores and depression scores did not differ significantly between patients with angina and those with ischemic heart failure.

MacNew questionnaire item characteristics (Table 3)

The missing MacNew item rate ranged from 0% (shortness of breath item) to 108 (39.1%) in patients with angina and 77 (49.7%) in patients with ischemic heart failure (sexual activity item for both groups). More than one MacNew item was missed by 42 of the patients (9.7%), with only one patient missing as many as seven items. Therefore, each MacNew subscale could be scored for every patient. There were no floor effects for the MacNew global score or subscales in patients with either angina or ischemic heart failure. Ceiling effects were observed in ≤1.3% of the patients on the global scale and the physical and emotional subscales; ceiling effects were observed in 16 (5.8%) of patients with angina and 6 (3.9%) in patients with ischemic heart failure on the social subscale for both groups.

MacNew factor structure (Table 4)

Our findings confirm the multidimensionality of the MacNew and support the established three-factor MI model [13,14]. After allowing measurement errors of the items to intercorrelate where appropriate, the three-factor model was supported for the combined data ($\chi^2/df = 3.66$; CFI = 0.938, RMSEA = 0.063, explained variance

Table 2 – MacNew, SF-36 physical component and mental component scales, and HADS scores in patients with angina and patients with ischemic heart failure.

	Angina	IHF	P value*
MacNew			
Global	5.3 ± 1.1	5.1 ± 1.2	0.045
Physical	5.3 ± 1.2	4.9 ± 1.4	0.003
Emotional	5.3 ± 1.1	5.2 ± 1.2	0.434
Social	5.5 ± 1.2	5.1 ± 1.4	0.001
SF-36			
PCS	39.7 ± 11.3	35.8 ± 10.1	0.001
MCS	49.5 ± 10.8	49.1 ± 10.9	0.715
HADS			
Anxiety	5.8 ± 3.5	5.4 ± 3.4	0.336
Depression	4.6 ± 3.5	5.1 ± 3.8	0.303

HADS, Hospital Anxiety and Depression Scale; IHF, ischemic heart failure; MCS, mental component summary; PCS, physical component summary; SF-36, Short Form-36 Health Survey.

* Kruskal-Wallis H test.

Table 3 – MacNew global and subscale floor and ceiling effects, internal consistency (Cronbach α), and test-retest reliability in patients with angina and patients with ischemic heart failure.

	MacNew			
	Global	Physical	Emotional	Social
Angina				
Floor effects, %	0	0	0	0
Ceiling effects, %	0.4	0.4	0.4	5.8
Cronbach α	0.96	0.93	0.94	0.94
ICC (95% CI) (n = 62)	0.72 (0.57–0.82)	0.70 (0.55–0.81)	0.75 (0.62–0.84)	0.72 (0.57–0.82)
Ischemic heart failure				
Floor effects, %	0	0	0	0
Ceiling effects, %	0.6	1.3	0.6	3.9
Cronbach α	0.97	0.94	0.95	0.95
ICC (95% CI) (n = 22)	0.85 (0.68–0.94)	0.90 (0.68–0.96)	0.78 (0.55–0.90)	0.86 (0.69–0.94)

CI, confidence interval; ICC, intraclass correlation.

45.9%), for patients with angina (AP: $\chi^2/df = 2.41$, CFI = 0.918, RMSEA = 0.072, explained variance 46.1%), and for patients with ischemic heart failure (IHF: $\chi^2/df = 2.08$, CFI = 0.903, RMSEA = 0.080, explained variance 46.5%). The intercorrelation of the factors ranged from 0.61 to 0.72. In both of the original MacNew factor

analyses based on patients with MI [13,14], a high proportion of social subscale items (10 of 13) cross-loaded with more than one subscale with factor loadings ≥ 0.40 . In the current analysis, none of the social subscale items cross-loaded in the physical or emotional subscales with loadings ≥ 0.40 in patients with angina; only

Table 4 – Confirmatory factor analysis for each MacNew item in patients with angina and ischemic heart failure.

MacNew item	Diagnosis					
	Angina			Ischemic heart failure		
	Emo	Phys	Soc	Emo	Phys	Soc
1. Frustrated	0.78	—	—	0.81	—	—
2. Worthless	0.64	—	0.26	0.79	—	0.13
3. Confident	0.60	—	—	0.65	—	—
4. Down in the dumps	0.85	—	—	0.87	—	—
5. Relaxed	0.78	—	—	0.76	—	—
6. Worn out	0.41	0.36	—	0.40	0.48	—
7. Happy with personal life	0.77	—	—	0.72	—	—
8. Restless	0.69	—	—	0.78	—	—
9. Shortness of breath	—	0.68	—	—	0.83	—
10. Tearful	0.63	—	—	0.65	—	—
11. More dependent	—	—	0.65	—	—	0.67
12. Social activities	0.05	0.35	0.30	0.32	0.32	0.11
13. Less confidence in you	0.29	—	0.49	0.44	—	0.38
14. Chest pain	—	0.41	—	—	0.53	—
15. Lack self-confidence	0.54	—	0.33	0.69	—	0.20
16. Aching legs	—	0.40	—	—	0.65	—
17. Sports/exercise limited	—	0.99	—	—	0.64	0.33
			0.15			
18. Frightened	0.72	—	—	0.78	—	—
19. Dizzy or lightheaded	—	0.45	—	—	0.43	—
20. Restricted or limited	—	0.93	—	—	0.67	0.34
			0.07			
21. Unsure about exercise	—	0.68	0.08	—	0.46	0.42
22. Overprotective family	—	—	0.55	—	—	0.56
23. Burden on others	0.20	—	0.68	0.42	—	0.46
24. Excluded	—	0.47	0.38	—	0.30	0.61
25. Unable to socialize	—	0.46	0.38	—	0.55	0.33
26. Physically restricted	—	0.97	—	—	0.66	0.36
			0.07			
27. Sexual activity	—	—	0.49	—	—	0.55
Variance explained, %	19.5	18.3	8.3	23.2	14.1	9.2

Factor loading items shown in bold type differ from original factor loading in patients with myocardial infarction.

Emo, emotional subscale; Phys, physical subscale; Soc, social subscale.

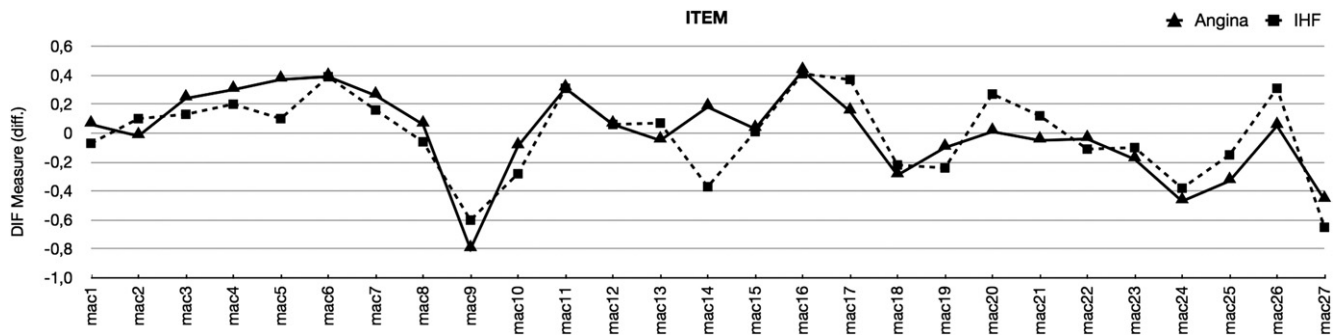


Fig. 1 – Differential item function for angina (AP) and heart failure (HF) patients. Differential item functioning (DIF) measure is presented in logits.

one of the social subscale items (item 21) cross-loaded in the physical subscale with a loading ≥ 0.40 in patients with ischemic heart failure. Item 27 about sexual activity, which was not part of the original factor analysis [14], fitted best with the social subscale. No DIF was observed for diagnosis, except for item 14 (DIF = -0.55 logits, $t(-6.21)$, $P < 0.001$, Fig. 1).

MacNew reliability (Table 3)

Internal consistency reliability of the MacNew global and each subscale was confirmed with all Cronbach α values >0.90 in patients with each diagnosis. As a measure of test-retest reliability, the ICC was always ≥ 0.70 , ranging from 0.70 (physical subscale) to 0.75 (emotional subscale) in patients with angina and from 0.78 (emotional subscale) to 0.90 (physical subscale) in patients with ischemic heart failure.

MacNew convergent validity (Table 5)

The correlations between similar MacNew and SF-36 scales (MacNew physical and PCS; MacNew emotional and MCS) were significant ($P < 0.001$), strong, and in the hypothesized direction. The correlations between dissimilar MacNew and SF-36 scales were significantly lower than between the similar scales (all one-sided P values <0.05). Taken together, these results confirm the convergent validity of the MacNew scales in patients with angina and ischemic heart failure.

MacNew discriminative validity (Table 6)

Discriminative validity of the MacNew was confirmed for each criterion ($P < 0.001$) in patients with angina and in patients with ischemic heart failure. In addition, all MacNew score differences exceeded the MID criterion of ≥ 0.5 between 1) the two diagnostic groups, 2) those improving or staying the same and those deteriorating on the SF-36 health transition item (always >0.88 in patients with angina and >1.24 in patients with ischemic heart failure), 3) those with and without anxiety (always >1.02 in patients with angina and >1.27 in patients with ischemic heart failure), and 4) those with and without depression (>1.45 in patients with angina and >1.91 in patients with ischemic heart failure).

Discussion

The English-language MacNew Heart Disease HRQoL questionnaire meets the recommended psychometric criteria for the conceptual model, reliability, validity, interpretability, and burden [38] in patients with either angina or ischemic heart failure. The expected patterns in MacNew global and each subscale scores were confirmed as patients with ischemic heart failure had poorer scores than patients with angina. These findings substantiate val-

idation reports on the MacNew in other languages in patients with angina and ischemic heart failure [24,26] as well as in patients with MI [13,14,16,21,26], providing support for the notion of the MacNew as a core IHD disease-specific HRQoL questionnaire.

The three-factor physical, emotional, and social subscale structure of the original English MacNew in patients with MI was confirmed in these patients with either angina or ischemic heart failure. In patients with angina, 46.1% of the total observed variance was explained, with 46.5% explained in patients with ischemic heart failure. The results of this confirmatory factor analysis indicate that the emotional and physical subscales are most consistent with the original factor structure identified in patients with MI [14]; only two emotional items (items 13 and 23) and one physical item (item 6) in patients with angina and only one physical subscale item (item 24) in patients with ischemic heart failure differed from the original factor analysis. Cross-loadings of ≥ 0.40 were allowed in the original model with 11 of the 13 social subscale items associated with either physical or emotional items [14], none of which were substantiated in the current study in patients with either angina or ischemic heart failure. In fact, the item about social activities (item 12) showed cross-factor loadings of <0.40 , which is quite different from the original model in which it was the only item with cross-loadings of ≥ 0.40 on all three subscales [14].

Table 5 – Convergent validity of the MacNew physical and emotional subscales with the SF-36 physical component and mental component scales in patients with angina ($n = 262$) and patients with ischemic heart failure ($n = 147$).

	MacNew physical subscale	MacNew emotional subscale	One-sided P value*
Angina			
SF-36 PCS	0.728 [†]	0.510 [†]	<0.001
SF-36 MCS	0.490 [†]	0.731 [†]	<0.001
One-sided P value*	<0.001	<0.001	
Ischemic heart failure			
SF-36 PCS	0.743 [†]	0.632 [†]	0.035
SF-36 MCS	0.584 [†]	0.750 [†]	0.004
One-sided P value*	0.007	0.026	

Strong correlations, $r \geq 0.50$.

SF-36 MCS, Short Form-36 Health Survey mental component summary; SF-36 PCS, Short Form-36 Health Survey physical component summary.

* Steiger's test for comparing Pearson correlation coefficients.

[†] Pearson correlation coefficients; P values <0.001 .

Table 6 – Discriminant validity of MacNew global score and subscale scores by SF-36 health status transition and HADS anxiety and depression in patients with angina and patients with ischemic heart failure.

	MacNew			
	Global	Physical	Emotional	Social
Angina				
SF-36 health transition				
Improve	5.62 ± 0.9*	5.67 ± 1.0*	5.55 ± 1.0*	5.84 ± 1.0*
No change	5.61 ± 0.8†	5.53 ± 0.9†	5.56 ± 0.8†	5.89 ± 1.0†
Deteriorate	4.65 ± 1.2	4.51 ± 1.3	4.66 ± 1.3	4.73 ± 1.3
Anxiety				
No	5.63 ± 0.9	5.53 ± 1.1	5.65 ± 0.9	5.80 ± 1.0
Yes	4.49 ± 1.1‡	4.58 ± 1.3‡	4.32 ± 1.1‡	4.77 ± 1.4‡
Depression				
No	5.63 ± 0.8	5.56 ± 1.0	5.63 ± 0.8	5.83 ± 0.9
Yes	4.11 ± 1.0‡	4.10 ± 1.2‡	3.92 ± 1.0‡	4.24 ± 1.3‡
Ischemic heart failure				
SF-36 health transition				
Improve	5.51 ± 0.9*	5.41 ± 1.2*	5.57 ± 1.0*	5.51 ± 1.1*
No change	5.51 ± 0.9†	5.29 ± 1.2†	5.60 ± 1.0†	5.60 ± 1.2†
Deteriorate	4.20 ± 1.1	3.88 ± 1.2	4.33 ± 1.2	4.05 ± 1.3
Anxiety				
No	5.41 ± 1.0	5.16 ± 1.3	5.56 ± 0.9	5.38 ± 1.2
Yes	3.95 ± 1.2‡	3.88 ± 1.3‡	3.82 ± 1.2‡	3.96 ± 1.5‡
Depression				
No	5.53 ± 0.9	5.36 ± 1.0	5.62 ± 0.8	5.56 ± 1.1
Yes	3.61 ± 0.8‡	3.27 ± 0.8‡	3.70 ± 1.0‡	3.44 ± 0.9‡

Values shown are mean ± SD. Analysis of variance (Welch test) or Kruskal-Wallis H test.

HADS, Hospital Anxiety and Depression Scale; SF-36, Short Form-36 Health Survey.

* Improve vs. deteriorate; $P < 0.05$.

† No change vs. deteriorate; $P < 0.05$.

‡ $P < 0.001$ in each diagnosis.

Item 27 about sexual activity was not part of the original factor structure [13,14] and, consistent with more recent international factor analysis studies [17, 21,23], fell into the social subscale rather than the physical subscale. A potential explanation for these findings is that the MacNew social items in general relate to social situations, either in a physical or interpersonal (emotional) context. These observations and concerns expressed previously about the factor structure of the MacNew [47,48] suggest that revisiting the MacNew from both a modeling perspective allocating items only to their main subscale and an item reduction perspective would be productive. This is in the process of being addressed. No differential item function was detected except for item 14. Item 14 addresses “how often during the past two weeks have you experienced chest pain while doing your day-to-day activities,” which was more likely to be endorsed by angina patients than ischemic heart failure patients.

Consistent with MacNew internal consistency reports in other languages [17,19,21–27], the Cronbach α was >0.90 on all scales in each diagnosis allowing for both group and individual HRQoL comparisons [38,49]. When administered twice, 14 days apart, test-retest reliability was confirmed in both diagnoses with an ICC >0.70 on all MacNew scales, also consistent with MacNew reports in other languages [22–24,26]. The lower test-retest reliabilities observed in patients with angina than in those with ischemic heart failure are most likely explained by the fluctuating nature of chest pain, even when well managed.

Convergent and discriminative validity of the MacNew was confirmed in patients with angina or ischemic heart failure. Similar MacNew and SF-36 scales (MacNew physical and PCS; MacNew emotional and MCS) had significantly high correlations. Dissimilar scales (MacNew physical and MCS; MacNew emotional and PCS) had significantly lower correlations than those of the similar

scales. The MacNew discriminated significantly by SF-36 health transition status, anxiety, and depression in both diagnostic groups. Patients with perceived health deterioration over the past year had significantly poorer MacNew global HRQoL and subscale scores than patients whose health had improved or stayed the same, with the difference exceeding the MacNew MID criterion of 0.5 points [36]. Similar MacNew observations were observed by the presence or absence of anxiety or depression, with the differences also exceeding the MID criterion in each instance. As an extension of these observations, the sample size required to demonstrate HRQoL differences between depressed and nondepressed patients with the specific MacNew HRQoL instrument would be only 40% of that estimated for the generic SF-36 HRQoL instrument (MacNew, $n = 8$ per group vs. SF-36, $n = 22$ per group), and this observation holds true for depression and for health transition status. This is important in terms of the potential usefulness of the MacNew because sample size is a major consideration when designing high-cost randomized trials.

Item relevance and minimal respondent and administrative burden are fundamental to the acceptance, implementation, and utilization of HRQoL instruments by patients, clinicians, and researchers [38]. That only 1 of the 431 patients missed no more than 7 of the 27 MacNew items in this study clearly demonstrates the relevance of items to patients, and MacNew global and subscale scores could be calculated for each of the 431 patients. Patients with cardiovascular disease frequently report fatigue [50]. “Feeling worn out” (MacNew item 6) was reported to be the number one problem by patients in both diagnostic groups in the current study, suggesting that fatigue can be considered a potential treatment focus for many patients with angina or ischemic heart failure. Finally, the self-administered MacNew is typically completed in

<10 minutes and is simple to score, resulting in minimal respondent and administrative burden [35].

The major limitation to this study is that the parent HeartQoL Project was designed as a cross-sectional survey for recruiting convenience samples of patients at each site [28]. As a result, we are unable to generate and report responsiveness statistics for the MacNew in these patients with either angina or ischemic heart failure. Although some ceiling effect was observed on the social subscale, the minimal floor and ceiling effects on the subscales should permit measurement of change, both deterioration and improvement, in HRQoL. The MacNew consistently has been shown to be responsive after different treatment options in patients with angina, myocardial infarction, or ischemic heart failure such as cardiac rehabilitation [24,51–56], revascularization [57,58], and medication [59], and we see no reason why the MacNew would not be responsive in other patients with angina or ischemic heart failure.

The results of this report in patients either with angina or ischemic heart failure demonstrate that the English version of the MacNew meets the psychometric standards for measurement, reliability, validity, interpretability, item relevance, and burden recommended for HRQoL instruments [38], and, although responsiveness could not be evaluated, this has been repeatedly demonstrated in other studies in patients with either angina or ischemic heart failure. This study extends previous international validation studies in other languages in patients with angina, MI, and ischemic heart failure [24,26], substantiating the suggesting of the MacNew as a potential core IHD-specific HRQoL instrument. A core IHD-specific HRQoL questionnaire will provide a better understanding of the range in HRQoL in patients with IHD that would potentially optimize clinical service provision and clinical medicine and social science outcome research efforts when assessing HRQoL or making HRQoL outcome comparisons across patients with angina, MI, or ischemic heart failure.

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